IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	S. Bailey, et al.	Attorney Docket:	6006-009
Serial No.:	09/783,633	Examiner:	C. Miller
Filed:	February 14, 2001	Art Unit:	3738
Confirmation No.:	2694	Customer No.:	29,335

Title: *In Vivo* Sensor and Method of Making Same

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SUBMISSION OF APPLICANT'S REPLY BRIEF

Dear Sir or Madam:

Applicant submits herewith Applicant's Reply Brief in accordance with 37 C.F.R. §41.41 in response to the Examiner's Answer dated March 25, 2011 (hereinafter "Examiner's Answer"). Applicant does not believe any additional fees are due in the Reply Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000.

REPLY BRIEF

1. Status of Claims

Claims 1-67, 70 and 79 have been cancelled. Claims 68, 69 and 71-76 are pending and stand rejected under 35 U.S.C. §102(b), §102(e) and §103(a). Claims 77, 78 and 80-85 are pending and stand rejected under 35 U.S.C. §103(a). The rejections of claims 68, 69, 71-78 and 80-85 are under appeal. Clams 68, 69, 71-71-78 and 80-85 are set forth in their entirety in Applicant's Appeal Brief dated January 27, 2011.

2. Grounds of Rejection to be Reviewed on Appeal

Whether claims 68, 69 and 71-76 are unpatentable under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) over U.S. Patent No. 5,601,593 to Freitag.

Whether claims 68, 69 and 71-76 are unpatentable under 35 U.S.C. §102(e) or, in the alternative, under 35 U.S.C. §103(a) over U.S. Patent No. 6,406,493 to Tu et al. (hereafter Tu).

Whether claims 77-78 and 80-85 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,591,197 to Orth et al. (hereafter Orth) in view of U.S. Patent No. 5,562,641 to Flomenblit et al. (hereafter Flomenblit).

The Examiner has withdrawn the rejection of claims 77, 78 and 80-85 as being unpatentable under 35 U.S.C. §103(a) over Freitag in view of U.S. Patent Application Pub. No. 2007/0255395 to Pollock et al. (hereafter Pollock). Examiner's Answer, page 3, lines 16-20.

3. Argument

I. The Examiner's anticipation rejection of claims 68, 69 and 71-76 under 35 U.S.C. §102(b) over *Freitag* is improper and should be withdrawn.

The Examiner has failed to establish that *Freitag* anticipates the claim because *Freitag* does not teach, expressly or implicitly, (a) the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; (b) the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; and (c) the element of a detection mechanism configured to detect the change in the geometry of the in vivo sensor device. Applicant submits that independent claim 68 and claims dependent therefrom, specifically claims 69 and 71-76, are patentable over the prior art cited and of record.

a. *Freitag does not teach or disclose the plurality of structural elements including a first region being composed of a first material and a second region being composed of a second material*

The Examiner alleged the following with respect to Freitag:

> The claims do not require EACH structural member to be made of two materials. The claims instead require the collection of structural members (the plurality of structural members) to comprise two different regions/materials. No claim limitations are present as to where exactly these two regions of different materials are located.

Examiner's Answer, page 8, lines 18-22. The Applicant again highlights the language of Claim 68, which states "the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a first transition coefficient" and "the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature." The Examiner takes great liberty in the claim construction of Claim 68 beyond the bounds of broadest reasonable interpretation. "Plurality" means "more than one;" however, the Examiner appears to construe the plurality of structural elements as "some structural members" may have a first material and "other structural members" have a second material, wherein the plurality of structural elements are different structural members. Examiner's Answer, Page 9, lines 1-2. To be clear, "plurality" does not mean a first structural element, a second structural element, nor does "plurality" delineate which "structural elements" include the particular "first material" or "second material." Each and every "structural element" includes a first material and a second material, as claim 68 does not state "some structural members" include a first material and "other structural members" include a second material. The Applicant remains baffled at how the Examiner can reconstruct the limitations of Claim 68 to fit the disclosure of Freitag for a proper §102 rejection.

Again, Claim 68 requires that the plurality of structural elements include "a first region being composed of a first material" and "a second region being composed of a second material." The plurality of structural elements themselves require a first region of a first material and a second region of a second material, it is not a first structural element being composed of a first material and a second different structural element being composed of a second material, as the Examiner has misconstrued and applied to Freitag. As the Examiner notes, Freitag discloses separate wires 3, 4, arranged in a zig-zag configuration, whereby the stent includes individual

rings A, B with different shape memories. Freitag, Col. 4, lines 16-25. Freitag clearly indicates that such wires are linked in the support structure or the wires may be connected to each other, which indicates that the wires 3, 4 are separate structural elements, as no structural member would require a linking or connecting element if it was a single structural member. While Claim 68 includes "a plurality of structural elements," the plurality merely means that there is more than one structural element. Still, each structural element must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material, the second material having a second transition temperature" higher than the first transition temperature. The Examiner's misconstruction of Claim 68 has led to an improper §102 rejection of Claim 68, as Freitag fails to disclose each and every limitation of Claim 68.

b. *Freitag does not teach or disclose the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature*

Freitag does not teach or suggest that "the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature," as to render Claim 68 anticipated. Again, Freitag discloses a stent with a support structure 2 composed of different and discrete wires 3 and 4 arranged in a zigzag configuration to form individual rings A, B with different shape memories. Freitag, Col. 4, lines 16-24. As noted above, each structural element of Claim 68 must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material." What follows for Claim 68 is that the "change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature" is on the structural element itself and the change in geometry of the second region is not on a separate or different structural element or wire as the Examiner presupposes. Again, "plurality" merely means that there is more than one structural element for Claim 68, not that there are separate structural elements that include the first region or include the second region. As such, Freitag is inappropriate to render Claim 68 anticipated as failing to disclose each and every limitation.

c. *Freitag does not teach or disclose for* ex vivo *detection of the change in geometry of the in vivo sensor*

An applicant is entitled to be his or her own lexicographer and may rebut the presumption

that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). MPEP § 2111.01(IV); *see In re Paulson* 30 F.3d 1475, 1480 (Fed. Cir. 1994). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998).

As noted by the Examiner, the only instance in which *Freitag* enables observation of the stent at any time during or after placement of the stent is by use of an endoscope. The Examiner was correct in saying that the optical abilities of an endoscope provide for viewing the proper positioning of the stent. This ability, however, does not provide the functionality required by Claim 1. The Applicant, at every point in the application, has described the detection mechanism as described in Claim 68 as an *ex vivo* device. The methods employed by the described mechanisms include radiographic imaging, ultrasound imaging, magnetic resonance imaging, and RF imaging. *See* P. 14. line 29 - P. 15, lines 1-2. Every one of these methods has at least one application that is an *ex vivo* procedure. Moreover, the Applicant specifically stated:

> Generally, the inventive endoluminal sensor consists of a sensor which is integral with an implantable endoluminal device, such as [a] stent, and which is configured to respond either mechanically, electronically, electromagnetically, or chemically, to cause a mechanical, electrical, electromechanical or chemical change at the sensor and/or the endoluminal device **which is detectable *ex vivo* using non-invasive detection methodologies such as radiography, ultrasonography, magnetic resonance imaging, or radio frequency detection.**

P. 7, lines 11-16 (emphasis added). This statement demonstrates the Applicant clearly considered the detection mechanism to be an *ex vivo* device, and the strength with which the statement is made requires that the only reasonable interpretation of the detection mechanism of Claim 68 be an *ex vivo* device. The explicitness with which the Applicant stated that the detection mechanisms were to be *ex vivo* devices is more than sufficient to inform a person of skill in the art that *in vivo* devices are not to be included within the scope of detection mechanisms embodied by this invention.

The Examiner has provided only a signal potential detection mechanism from *Freitag*, an endoscope. Endoscopes are *in vivo* by definition, requiring entrance to a body to provide images from within the body. After entering the body, the endoscope would only detect a single state of

the stent disclosed in Freitag and not be "configured to detect the change in the geometry or conformation of the in vivo sensor device," as Claim 68 requires. Any in vivo detection would merely show an image of the stent, not a change in geometry or conformation of the in vivo sensor device. There are no other detection mechanisms taught or suggested by *Freitag*. As such, *Freitag* does not teach or fairly suggest an *in vivo* sensor that undergoes a transition where that transition is detectable by an *ex vivo* detection mechanism. Therefore, *Freitag* does not teach or suggest every element of Claim 68, hence it does not anticipate Claim 68. For at least this reason, the Applicant submits that independent Claim 68, as well as Claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

Moreover, the observational capabilities for the endoscope the Examiner has provided could not provide the sensitivity or the capacity to detect first and second regions that transition from a first state to a second state. Claim 68 is directed to "a plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, wherein the second transition temperature and the second transition coefficient allows for a change in the geometry or conformation of the second region in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device." The application sheds light on the plurality of structural elements and the in vivo sensor device being "in vivo sensor device 30 in the form of an endoluminal stent adapted for non-invasive vascular modeling and imaging and the inventive in vivo sensor device 30 comprises a plurality of structural elements 32, 36 that serve to define walls of the sensor device 30." P. 21, lines. 21-25. The endoscope would not be "configured to detect the change in the geometry or conformation of the in vivo sensor device," as stents are on the order of millimeter in length and diameter.

An endoscope is an instrument used to examine the interior of a hollow organ or cavity of the body and endoscopes are inserted directly into the organ. Nothing in the Examiner's reasoning nor capabilities of the endoscope could be "configured to detect the change in the

geometry or conformation of the in vivo sensor device." Any in vivo detection would only detect a single state of the stent in Frietag, if that.

For at least these reasons, the Applicant submits that Claims 68, 69 and 71-76 are patentable over Freitag, for Freitag fails to disclose each and every limitation of independent Claim 68.

II. The Examiner's obviousness rejection of claims 68, 69 and 71-76 under 35 U.S.C §103(a) over Freitag is improper and should be withdrawn

For similar reasons to the argument against the Examiner's §102(b) rejection under Freitag, the §103(a) rejection is improper, as Claims 68, 69, and 71-76 are distinguishable, from and patentable over, the prior art cited and of record and for Freitag failing to teach or fairly suggest each and every limitation of independent Claim 68. First, as argued above, Freitag does not teach or suggest the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; and the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature. Nothing in Freitag teaches or fairly suggests to one of ordinary skill in the art that the individual wire structural elements include a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, or the second material having a second transition temperature higher than the first transition temperature or the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature. The Examiner uses inappropriate hindsight to reconstruct the Freitag reference to include the limitations of Claims 68, 69, and 71-76. Second, the Examiner's obviousness rejection appears to be related to the detection mechanism discussed by the Examiner. However, Freitag does not teach or fairly suggest to one of ordinary skill in the art (a) an *ex vivo* detection mechanism to detect a change in the geometry or (b) conformation of the sensor device such as an *ex vivo* sensor would not have been obvious to one of ordinary skill in the art at the time the invention was made because the device of *Freitag* was not a sensor as described by the Applicant.

a. *Freitag does not teach or disclose the second material responding to at least one physiological condition for Claims 72-76*

The Examiner alleged that "physiological events" are not claimed. Examiner's Answer,

page 11, line 9. The invention of Claim 68 and Claims 72-76 are designed to detect clinically significant physiological conditions or events and these physiological conditions or events are claimed by Claims 72-76. Claim 72 claims "at least one physiological condition," Claim 73 claims the physiological condition is "fluid flow rate," Claim 74 claims the physiological condition is "temperature," Claim 75 claims the physiological condition is "plaque," and Claim 76 claims the physiological condition is an "electrochemical change." Nothing in Freitag teaches or fairly suggests to one of ordinary skill in the art that the wires 3 and 4 senses any physiological condition, let alone, a physiological condition selected from "fluid flow rate," "plaque," or "electrochemical change." Freitag discloses that the application of heat can be effected by a balloon with warm water or cold applied by the application of ice water. Freitag, Col. 3, lines 5-10. This application of heat or water does not come within the bounds of a physiological condition, i.e. the dealing with the functions and activities of living organisms and their parts, including all physical and chemical processes.

The presence of an *in vivo* device, such as an endoscope as taught by *Freitag*, would necessarily affect and interfere with the operation of a device intended to measure the *in vivo* status of these physiological properties. An *ex vivo* detection mechanism is necessary to measure these physiological properties without affecting them. *Freitag* does not teach or suggest such a detection mechanism. As such, the Examiner has applied inappropriate hindsight to reconstruct Applicant's in vivo sensor device with the disclosure of *Freitag*, which does not include an *ex vivo* detection mechanism.

For at least these reasons, the Applicant submits that independent Claim 68, as well as Claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

b. *The device in* Freitag *is not a sensor as enabled by Applicant.*

Contrary to the Examiner's assertion, *Freitag* does not disclose a sensor as required by Claim 68. The Applicant described the invention as suitable for monitoring clinically significant physiological events. Present application, P. 4, lines 22-23. Indeed, the creation of the sensor is explicitly stated to be for sensing specific physiological conditions. Present application, P. 5, lines 10-14. Critical to this point is that the sensor is for monitoring *in vivo* conditions; any change in the geometry or conformation of the sensor is a result of changes in conditions of the human subject, not a result of foreign means. Indeed, a device is not a "sensor" if it changes the

conditions it is purported to be sensing.

The device in *Freitag* is described as a stent "whose restoring force can be changed after having been placed in the body." This phrase fairly describes the purpose of the invention as a stent that can be expanded and retracted *in vivo*; it is not described as a device for monitoring physiological conditions. Indeed, the Examiner stated in her argument that an endoscope may be used for "ensuring proper expansion had taken place." This belies the improper inference the Examiner is attempting to read into *Freitag*. As a sensor, the device of Claim 68 is not intended for the change in geometry or conformation to occur; it is only to occur pursuant to certain triggering physiological changes. Conversely, in *Freitag*, the changes in geometry and conformation are part of a controlled procedure in which the *in vivo* device can be selectively expanded or contracted, regardless of the physiological conditions surrounding the device, to achieve a desired restorative force. Therefore, the Examiner's characterization of *Freitag* as a sensor is improper.

Accordingly, the Examiner has not demonstrated Claim 68 to be obvious under *Freitag*. For at least these reasons, the Applicant submits that independent Claim 68, as well as Claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

III. The Examiner's anticipation rejection of claims 68, 69 and 71-76 under 35 U.S.C. §102(e) over Tu is improper and should be withdrawn.

The Examiner has failed to establish that Tu anticipates the claim because Tu does not teach, expressly or implicitly, (a) the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; (b) the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; and (c) ex vivo detection of the change in geometry of the in vivo sensor. Applicant submits that independent Claim 68 and claims dependent therefrom, specifically Claims 69 and 71-76, are patentable over the prior art cited and of record.

a. *Tu does not teach or disclose the plurality of structural elements including a first region being composed of a first material and a second region being composed of a second material*

The Examiner alleged the following with respect to Tu:

> The claims do not require EACH structural member to be made of two materials. The claims instead require the collection of structural members (the plurality of structural members) to comprise two different regions/materials. No claim limitations are present as to where exactly these two regions of different materials are located.

Examiner's Answer, page 11, lines 13-17. The Applicant again highlights the language of Claim 68, which states "the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a first transition coefficient" and "the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature." The Examiner takes great liberty in the claim construction of Claim 68. "Plurality" means "more than one;" however, the Examiner appears to construe the plurality of structural elements as "some structural members" may have a first material and "other structural members" have a second material, where the plurality of structural elements are different structural members. Examiner's Answer, Page 9, lines 17-21. To be clear, "plurality" means "more than one;" "plurality" does not mean a first structural element, a second structural element, nor does "plurality" delineate which "structural elements" include the particular "first material" or "second material." Each and every "structural element" includes a first material and a second material, as Claim 68 does not state "some structural members" include a first material and "other structural members" include a second material. The Applicant remains baffled at how the Examiner can reconstruct the limitations of Claim 68 to fit the disclosure of Tu for a proper §102 rejection.

As the Examiner notes, Tu discloses a stenting element 13a and another stenting element 14a, whereby 13a is a first group of stenting elements and 14a is second group of stenting elements. Examiner's Answer, page 11, lines 17-21. Again, the stenting element 13 and the stenting element 14 are completely separate and discrete structural elements, as circular members 11a-11d are securely joined to adjacent circular members by the stenting elements 13a and 14a. Tu, Col. 6, lines 13-16. By joining the circular members through discrete and different stenting elements 13a and 14a, Tu teaches and suggests that the stenting elements 13a and 14a are not the same structural elements, and indeed have different purposes for the annuloplasty ring 12, structurally and otherwise. The Examiner's citation to locations of stenting element 13a and stenting element 14a remains locations on different structural elements. Examiner's Answer, page 11, line 21-page 12, line 2. On the contrary, Claim 68 includes "a plurality of structural

elements," the plurality merely means that there is more than one structural element. Still, each structural element must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material, the second material having a second transition temperature" for Claim 68. Tu, fails to disclose any single structural element 13, 14, or 11 as including a first region of the first material and second region of a second material, whereby the second material has a second transition temperature higher than the first material. The Examiner's misconstruction of Claim 68 has led to an improper §102 rejection of Claim 68 in light of Tu. As such, Tu fails to disclose each and every limitation of Claim 68.

b. *Tu does not teach or disclose the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature*

Tu does not teach or suggest that "the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature," as to render Claim 68 anticipated. Again, Tu discloses stenting elements 13a and 14a that connect different circular members 11 as to form a first group of circular members with stenting element 13a and a second group of circular members with stenting element 14a. As noted above, each structural element of Claim 68 must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material" having a second transition temperature higher than the first transition temperature. What follows for Claim 68 is that the "change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature" is on or within the structural element and the change in geometry of the second region is not on a separate or different structural element or wire as the Examiner presupposes or interprets. As such, Tu is inappropriate to render Claim 68 anticipated as fairly to disclose each and every limitation.

c. *Tu does not teach or disclose an* ex vivo *detection of the change in geometry of the in vivo sensor.*

Contrary to the Examiner's assertion, *Tu* does not disclose an *in vivo* sensor as required by Claim 68. Similar to the argument made above, *Tu* teaches the use of *in vivo* devices that inherently interfere with the physiological conditions surrounding the stent. Indeed, this is their intended purpose; *Tu* teaches devices to convey heat to the stent for the purpose of triggering the

change in geometry of the shape-memory material. Col. 3, lines 56-64; Col. 7, lines 52-67; Col. 8, lines 1-7. By intentionally causing the transition that results in the change in geometry or conformation of the device, *Tu* precludes itself from functioning as a sensor; if the detectable change in geometry is intentionally triggered, the device cannot be fairly considered to be monitoring the environment around the device for the triggering condition. Once the device has undergone the detectable transition, even if the triggering condition occurs, the device has already transitioned, thus the device cannot convey the occurrence of the triggering condition.

The Examiner artificially, and inaccurately, delineates the heat conveying sources into their heat conveying function and their potential imaging function:

> Tu makes use RF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc, which are considered inherently to have a display on them for the surgeon to see inside the body. An image of the first configuration and an image of the second configuration will be displayed to the surgeon.

Examiner's Answer, Page 12, lines 16-19. First, the energies disclosed by Tu are not coupled nor shown to be operable with any type of imaging device or display for the Examiner to contend that such energies inherently have a display on them. Tu only discloses a source of heat, whereby the source may be selected from a group consisting of radiofrequency energy, heated balloon, infrared energy, ultrasound energy, and laser energy. Tu, Col. 3, lines 60-65. These sources of heat are not inherently capable of functioning as a detection mechanism and the Applicant objects to the Examiner indicating so.

And, the Examiner alleged that "physiological events" are not claimed. Examiner's Answer, page 13, line 4. The invention of Claim 68 and Claims 72-76 are designed to detect clinically significant physiological conditions or events and these physiological conditions or events are claimed by Claims 72-76. Claim 72 claims "at least one physiological condition," Claim 73 claims the physiological condition is "fluid flow rate," Claim 74 claims the physiological condition is "temperature," Claim 75 claims the physiological condition is "plaque," and Claim 76 claims the physiological condition is an "electrochemical change." Nothing in Tu teaches or fairly suggests to one of ordinary skill in the art that the stenting elements 13a or 14a senses any physiological condition, let alone, a physiological condition selected from "fluid flow rate," "plaque," or "electrochemical change." Tu teaches devices to convey heat to the stent for the purpose of triggering the change in geometry of the shape-memory material. Tu, Col. 3, lines 56-64; Col. 7, lines 52-67; Col. 8, lines 1-7. The Examiner

contends that these heat sources are both the detection mechanism and the change in physiological condition. Examiner's Answer, page 13, lines 4-11. The Examiner cannot have it both ways and more importantly, the Examiner has it wrong on both accounts. RF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc. are not physiological conditions, i.e. physiology is all the functions of a living organism or any of its parts. As such, Tu is improper to render Claims 72-76 anticipated as failing to teach or suggest detection of physiological conditions as required by the claims.

IV. The Examiner's obviousness rejection of claims 68, 69 and 71-76 under 35 U.S.C. §103(a) over Tu is improper and should be withdrawn.

For essentially the same reasons as stated above for the §102(e) rejection, the Examiner's rejection under §103(a) is improper. In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). As shown above, *Tu* does not teach or fairly suggest (a) the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; (b) the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; (c) the element of a detection mechanism configured to detect the change in the geometry of the in vivo sensor device; and (d) "at least one physiological condition" that is a "fluid flow rate," a "plaque," and an "electrochemical change," for Claims 72-76. Tu teaches the intentional transition of the device's shape memory material by imparting heat to the device, thereby preventing the device from functioning as a sensor. And the Examiner alleged that:

> The examiners position is that if not inherent that any of RF energy, IR engery, ultrasound, fiber optics have an image display, one would have been obvious such that the performing surgeon may view the application of heat and make ensure successful positioning as well as shape change/expansion.

The Examiner's blanket statement and conclusory argument that certain elements of Applicant's claims are well known in the art is inappropriate hindsight. The Applicant objects to the Examiner's blanket characterizations of the prior art reference in light of Applicant's claims, as the Examiner has not provided any evidence in support for such characterizations. The

Examiner uses §103 as a catchall for his §102 rejection of Claims 68, 69 and 71-76 in view of Tu; however, the Examiner's reasoning and rationale comes up grossly short. Any modification of *Tu* for RF energy, IR engery, ultrasound, fiber optics would be contrary to the teachings of *Tu* and cannot stand for any of the "at least one physiological condition" that is a "fluid flow rate," a "plaque," and an "electrochemical change;" hence, the Examiner's position is not a valid grounds for a §103(a) rejection. For at least these reasons, the Applicant submits that independent Claim 68, as well as Claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

V. The Examiner's obviousness rejection of claims 77, 78 and 80-85 under 35 U.S.C §103(a) over *Orth et al.* in view of *Flomenblit et al.* is improper and should be withdrawn.

The Examiner has failed to establish that Orth in view of Flomenblit renders Claim 77 obvious because: (a) the Examiner failed to establish a *prima facie* case against Claim 77; (b) Orth in view of Flomenblit fails to disclose or fairly suggest each and every limitation in Claim 77; and (c) the limitation of the second region, in its second position, projecting from the surface of the first region is not obvious in light of Orth in view of Flomenblit. Applicant submits that independent Claim 77 and claims dependent therefrom, specifically Claims 78, 80, 81, 82, 83, 84, and 85, are patentable over the prior art cited of record.

a. *The Examiner failed to establish a* prima facie *case against claim 77.*

Claim 77 includes the limitation "the first position [of the second region] is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature." More so, Claim 77 requires that "second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device." Underline added. The Examiner has not presented factual support that either *Orth* or *Flomenblit* teach or suggest these limitations, nor that the limitations would be obvious to one of ordinary skill in the art at the time of the invention. Indeed, the Examiner did not mention the limitation at all in her rejection of Claim 77 in the Final Office Action dated March 25, 2010. However, now the Examiner appears to allege in the Examiner's Answer that Orth in view of Flomenblit includes such limitations. Examiner's Answer, page 14, lines 1-16. The Examiner's characterization of Orth in view of Flomenblit should be treated as new grounds of rejections, accordingly. As such, the Applicant should be provided an opportunity to present new arguments

not disclosed in Applicant's Appeal Brief. Indeed, the Examiner even withdrew the rejections of Claims 77, 78 and 80-85 under 35 U.S.C §103(a) over Freitag in view of Pollack for not making out a *prima facie* case of obvious. Examiner's Answer, page 3, lines 16-20. For at least this reason, the Examiner's rejection of Claim 77 is improper and Claim 77 is patentable over the prior art cited of record.

Even so, the Examiner's characterization of Orth in view of Flomenblit remains flawed and improper. The Examiner alleged that:

> Orth discloses a piece meal stent with separate sections 11, 12, and 20/22, see figures 5 and 6. Orth expands sections 11 and 12 separate from section 20 as the two have different functions. Sections 11 and 12 expand to a larger diameter to be flush with the vessel wall. Section 20 moves to protrude further outward to pinch the vessel wall. The different sections are independent and may be deployed simultaneously OR at different times (col. 9, lines 1-12).

First, Orth does not disclose different sections that are independent and that may be deployed simultaneously or at different times. The Examiner cites to Col. 9, lines 1-12 of Orth to support such statement; however, Orth discloses that projecting barb 22 is formed when the first stent section 11 and second stent section 12 are forced closer together, thereby causing notched connecting member 20 to deform outwardly and thereby form projecting barb 22. The first stent section 11 and the second stent section 12 must be forced closer together in order to cause notched interconnecting member 20 to form projecting barb. Nothing in Orth indicates that first stent section 11, second stent section 12 or interconnecting member 20 can be deployed at different times. If first stent section 11 and second stent section 12 are not forced closer together, the notched interconnecting member 20 will not be deployed. As such, Orth does not disclose different sections that are independent and that may be deployed simultaneously or at different times.

Second, Orth does not disclose that first stent section 11, second stent section 12, or the notched connecting member 20 are independent, as the notched connecting member 20 connects both the first stent section 11 and the second stent section 12. Moreover, the first stent section 11 and the second stent section 12 themselves include a plurality of cylindrical elements 13 that are connected by connecting members 16. In fact, as expansion occurs, connecting members 16, which connect first stent section 11 to second stent section 12, are in tension but they cannot stretch and it is this tension between first stent section 11 and second stent section 12 that creates an opposite compressive force on the connecting member 20, which buckles at notch 22 and

shortens in length, thereby forming projecting barb 22. Orth, Col. 7, lines 27-33. The notched connecting member 20 will not protrude further outward without the action of the first stent section 11 and the second stent section 12.

Since Orth does not teach that first stent sections 11, second stent section 12, or the notched connecting member are independent or may be deployed at different times, any teachings of Flomenblit does not teach or suggest to one of ordinary skill in the art to modify any of the first stent section 11, second stent section 12, or notched interconnecting member 20 as to include different transition temperatures at different times, as the Examiner contends. Examiner's Answer, page 14, lines 12-17. What follows is that the deployment of the stent sections 11 and 12 do not product a stent that will change shape at two different times and the Examiner's reasoning and rationale are improper to render Claim 77 obvious as failing to disclose the limitations in Claim 77, as further explained below.

b. *Orth in view of Flomenblit does not teach or fairly suggest each and every limitation of Claim 77*

First, Orth and Flomenblit do not teach or fairly suggest that the "second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device," wherein the "first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature." The Examiner alleged that:

> Regions 11 and 12 expand from a first to a second diameter and region 20 projects radially outward in the form of barbs to engage tissue. Although the two may occur simultaneously as applicant has noted, they also may occur separately at different times (col. 9, lines 6-13).

Examiner's Answer, page 14, 20-page 15, line 1. Orth discloses that the projecting barb 22 is formed when first stent section 11 and second stent section 12 are forced closer together, thereby causing notched connecting members 20 to deform outwardly and thereby form projecting barb 22. Orth, Col. 9, lines 6-10. Thereafter, the stent can be expanded so that it expands from a first, low profile diameter to a second larger diameter to contact the vessel wall. Orth, Col. 9, lines 10-12, underlined added. Only after the projecting barb 22 has been formed by the first stent section 11 and the second stent section 12 forcing together, can the stent be expanded to a second larger diameter, this formation of the projecting barb 22 does not form in the second diametric state.

Again, Orth repeatedly mentions that only after the stent has been positioned at the site at which it will be implanted, is it expanded and projecting barbs 22 form during radial expansion. Orth, Col. 7, lines 52-55, Underlined added. In stark contrast, the second region of the Claim 77 changes from a first position to a second position in the second diametric state of the first material, where the first material expands from a first diametric state to a second diametric state, not during radial expansion. Orth specifically requires the notched connecting members to form the projecting barbs 22 when expansion occurs because connecting members 16 cannot expand to form a tension and opposite compressive force on the connecting member to buckle notch and shortens it length. Orth, Col. 7, lines 25-32. When the Orth stent is in a second diametric state, the connecting members cannot change from its deformed position that is coplanar with the surface of the first region to a second position that projects outwardly from the surface of the first region, because the Orth stent requires expansion to deform or buckle the notched connecting members 20. The connecting members 20 deform only during expansion of the stent from a first diametric state to a second diametric state. And even if one of ordinary skill of the art would take Flomenblit's different transitional temperatures and coefficients at different regions of the stent to control the expansion of the stent, as the Examiner inappropriately alleges, the connecting members 20 would, under a grossly misappropriate conclusion, deform to the projecting barb 22 state when the stent is in the expanded state and therefore have ability to pull or force stent sections 11 and 12 closer together in order to form the shortened notched members when the stent is already in an expanded state or second diametric state. Such a combination would render a stent wholly or partly inoperable. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As such, Orth in view of Flomenblit is insufficient to render Claim 77 obvious as failing to teach or fairly suggest each and every limitation of Claim 77.

Claim 77 requires that "the plurality of structural elements including a first region being composed of a first material" and "the plurality of structural elements including a second region being composed of a second material," where the second region changes from a first position to a second position and where the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region. The Examiner alleged that:

> [T]he claims do not require EACH wire to have two different regions/materials-instead the claims require the plurality of structural elements (grouping of all struts) to comprise a first and second region. Second region (struts 20) are shown coplanar with respect to first region (11, 12) in figure 5 and 5a; and second region (struts 20) are shown projecting away from first region (11, 12) in figure 6a.

Examiner's Answer, page 15, lines 13-17. Again, "plurality of structural elements" means "more than one structural element," it is not "a grouping of all struts," as the Examiner continues to misconstrue. The structural elements themselves require a first region and a second region. Orth discloses separate and discrete structural elements, none of which include a first region of a first material and second region of a second material and where the second region changes from a first position to a second position. The Examiner now cites notched connecting members 20 as the second region and first and second stent sections 11 and 12 as the first region. However, first and second stent sections 11 and 12 even include a plurality of cylindrical elements 13 that are connected by a plurality of cylindrical elements 16, where the notched connecting members 20 connect the first and second stent sections 11 and 12. Orth, Col. 6, lines 25-48, and Figs. 1-6. Notched connecting member 20 is a discrete and separate structural element, as it deforms to buckle and form barb 22, as compared the first and second stent sections 11 and 12, which are forced together to cause oppressive forces on connecting member 20 to buckle the notch 22. Neither the notched connecting member 20 or the first and second stent sections 11 and 12 include a second region composed of a second material that changes from a first position to a second position where the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region of the cylindrical element 13. Even if the Examiner contends that the notch 21 of the notched connecting member is a second region composed of a second material, notch 21 is cut into the notch connecting member and is not coplanar and does not assume a first position that is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region when the first region is in a second diametric state. As such, Orth is insufficient to render Claim 77 obvious in view of Flomenblit.

Additionally, the Examiner's motivation for combining Orth with Flomenblit is insufficient and improper. The Examiner argued that Orth's second elements (20) would have a first coplanar position after the first elements (13) radially expand and a second projecting position after elements 20 expand. However, the plurality of notched connecting members 20 in Orth are designed to buckle or deform during expansion of stent 10. Orth, Col. 6, lines 45-50.

To accomplish the proper deformation of notched connecting member 20, a notch 21 is cut into notched connecting member 20 to provide a weakened area and to allow deformation to take place at that point. *Id*. The Examiner reasons that it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Orth's piecewise stent (having first and second regions that expand at different times independently) with Flomenblit's teaching of using two different transitional temperatures to expand different portions of a stent at different times, in order to provide a stent with increased control over individual regions during implantation. This rationale is weak and improper hindsight. Flomenblit uses a band of two-way shape memory alloy of the kind used in accordance with the invention has two transition temperatures: a first transition temperature being above body temperature in which it changes from its soft state into its super-elastic state, and a second temperature, being below body temperature, in which it changes from the super-elastic state into the soft state. Col. 3, lines 2-11. Claim 77 requires that the "first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state" and "the second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device." Any first transition temperature for Flomenblit expands the stent for form 14 as it has in its super-elastic state, but the temperature is reduced below T_2, the second transition temperature, the diameter of the stent narrows as it assumes its form 16 in said soft state. If any element 20 in Orth would include the second transition temperature, element 20 would be in a soft state and shrink to narrow the distance between the connecting members 16, and not deform to buckle and form a barb as Orth requires. And in the alternative, if the connecting members 16 were in the second transition temperature and in a soft state, the connecting members could be "the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient" and expand from a first diametric state to a second diametric state. Indeed, element 20, if in the first transition temperature as one would presuppose, would not be able to buckle or deform, but would rather shrink and shorten the distance between any connecting struts in Orth's stent. Hence, the Examiner's motivation for combining Orth with Flomenblit is insufficient and improper hindsight.

c. *The limitation of the second region, in its second position, projecting from the surface of the first region is not obvious in light of Orth in view of Flomenblit.*

The Examiner alleged that:

> Second region (20) clearly is shown attached to first region (11 or 12) at lines pointing to 20a and 20b in fig.6a and is shown projecting away from its surface.

Examiner's Answer, page 15, lines 19-21. Fig. 6a in Orth shows that the projecting barb 22 is formed when the first stent section 11 and the second stent section 12 are forced closer together, thereby causing notched connecting member 20 to deform outwardly. Again, connecting member 20 does not "project outwardly from the surface of the first region," which Claim 77 requires. Connecting member 20 connects the first and second stent section 11 and 12, it does not project from the surface of the first and second stent sections 11 and 12. Orth teaches that connecting member 20 includes a first end 20a connected to the first stent section 11 and second end 20b connected to the second stent section 12. Orth, Col. 6, lines 45-51. Fig. 6a is a grossly inaccurate example of the first and second stent sections 11 and 12 being moved closer together. Figure 5a appropriately shows that the connecting member 20 connecting the first and second stent section 11 and 12, however, it remains to be seen how the connecting member 20 would be able to jump on top of the surface of the first and second stent section 11 and 12, as it is shown in Figure 6a, which would necessarily cause breakage of the notched connecting member 20.

Taking the teachings of *Orth* and *Flomenblit* together, one of ordinary skill in the art would not have arrived at the claimed invention of Claim 77. Claim 77 requires the second position of the second portion to "project outwardly from the surface of the first region." *Orth* explicitly defines the notched connection members 20 as connecting first and second sections 11 and 12 of the stent. The figures identified above depict the notched connecting members 20 disposed between the first and second sections. Critically, Fig. 2C clearly shows the notched connecting members projecting outward from the *plane* of the first section, but not projecting outward *from the surface* of the first section. Requiring that the second region project from the surface of the first region necessarily requires the second region be bound by the projection of the first surface. By definition, the notched interconnecting members cannot be bound by the projection of the surface of a first region; were that so, it could not connect the first and second sections, as is required by *Orth*. As such, one of ordinary skill in the art at the time of the invention would not conceive of the invention of Claim 77 in light of *Orth*, as that invention would be contrary to the teachings of *Orth*. For at least these reasons, applicant submits that

pending Claims 77, 78, and 80-85 are distinguished from and patentable over the prior art cited of record.

Finally, nothing in Orth indicates that the second position of the notched connecting member 20 would be detected by a detection mechanism. The Examiner alleged that:

> The change in stent length alone (shrinking as the hooks 20 angle outward) would be considered a detection of the change of configuration. Orth discloses use of guidewires with the stents, the guidewires considered inherent to have imaging capabilities which would detect the change in shape (the detection mechanism could even be considered the surgeon him or herself as they see the change in shape).

Examiner's Answer, page 16, lines 1-5. The Applicant cannot understand how the change in stent length and guidewires is a detection mechanism. Guidewires are used to in medical procedures to obtain safe access to blood vessels and other hollow organs. Still, any shrinkage of the stent coupled with a guidewire would detect the notched connecting members 20 penetrating the aortic wall. Orth, Col. 4, lines 3-7. Something that attaches to an aortic wall does not show it would be detectable by a detection mechanism, whereby Claim 77 requires that the "detection mechanism configured to detect the second position of the in vivo sensor device." More so, the Examiner hedges such obviousness statements, with the following:

> If not inherent that the guidewire or catheter system of Orth is used with an image display, it would have been obvious as these are well known features on guidewires and catheter systems so that the surgeon may watch the positioning and deployment of the implants to make sure they were successfully placed and actuated.

Examiner's Answer, page 16, lines 6-9. Such conclusory statement does not speak to the fact that the detection mechanism must detect the second position of the second region. Deployment of implants does not detect the projecting barbs 22 of the connecting member 20 as the Examiner alleges.

Finally, Claim 81 claims "at least one physiological condition," Claim 82 claims the physiological condition is "fluid flow rate," Claim 83 claims the physiological condition is "temperature," Claim 84 claims the physiological condition is "plaque," and Claim 85 claims the physiological condition is an "electrochemical change." Nothing in Orth in view of Flomenblit teaches or fairly suggests to one of ordinary skill in the art that the notched connecting member 20 senses any physiological condition, let alone, a physiological condition selected from "fluid

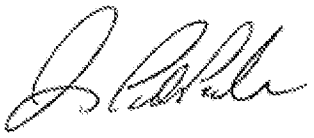
flow rate," "plaque," or "electrochemical change." For at least these reasons, the Applicant submits that independent Claim 77 and claims dependent therefrom, specifically Claims 78, 80, 81, 82, 83, 84, and 85, are patentable over the prior art cited of record.

Conclusion

An anticipation rejection under 35 U.S.C. § 102(b) or §102(e) requires that the cited prior art reference must disclose each and every claimed element. *Freitag* does not teach the use of a detection mechanism as defined by the Applicant, and neither *Freitag* nor *Tu* teach a device that functions as a sensor. The Examiner's characterizations of *Freitag* and *Tu* are contrary to the limitations of the Claims, making them improper bases for the §103(a) rejections. *Orth* in light of *Flomenblit* cannot be combined as suggested by the Examiner, hence their combination cannot serve as the basis for a §103(a) rejection. Finally, considering *Freitag* in light of *Pollock* does not overcome the deficiencies of *Freitag*. Thus, each of the Examiner's objections have been shown to be improper, and thus should be withdrawn.

Accordingly, the Applicant respectfully requests the Board withdraw the §102(b), §102(e), and §103(a) rejections of Claims 68, 69, and 71-76, and the §103(a) rejections of Claims 77, 78 and 80-85, and allow the above-identified application to proceed to allowance and issuance.

Respectfully submitted,



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May 25, 2011

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